REMARKS

Claims 25-40 are active in the present application.

At the outset, Applicants would like to thank Examiner Hines for the indication that the new matter rejection of Claims 33-40, the enablement rejection of Claims 25-32, an dthe indefiniteness rejection of Claims 25-32 have been withdrawn (paper number 24, page 2, paragraph 2). Reconsideration of the current grounds of rejection is requested in view of the following remarks.

The rejection of Claims 33-35 under 35 U.S.C. §102 over Thomas et al is traversed.

In the method of Claims 33-35, as amended above, a nucleic acid is bound to a polypeptide (antigen) and the nucleic acid bound polypeptide is subsequently fixed onto particles (see Claim 33). Following immobilization, the particles are allowed to react with a sample containing the antibody corresponding to the polypeptide (antigen).

In sharp contrast to the presently claimed invention, in Thomas et al, after the antigen-antibody reaction, a label-monomer attached to the antigen-antibody complex is subjected to additional polymerization, thereby separating the antigen-antibody complex from the free (i.e., unreacted) reactants (see Claim 1). In this method, the signal from the free labeled reactant is rendered very weak thereby decreasing the background. Therefore, even a trace amount of antigen may be measured with a high sensitivity. The antigen to be measured in the present invention is a nucleic acid-bound polypeptide. As previously stated, the present invention does not include and/or require a polymerization separation step.

The method of pending Claims 33-35 is also distinct from Thomas et al, in that it utilizes binding (i.e., agglutination) between the nucleic acid and the polypeptide (antigen)

through a nucleic acid-binding motif in the polypeptide so as to change the structure of the antigen. Accordingly, an increased ability of the antigen to bond with the corresponding antibody results from this agglutination. In the presently claimed invention, what is claimed is a method of measuring an antiboby.

At no point do Thomas et al disclose or suggest such an interaction or detection methods. The standard for determining anticipation requires that the reference "must teach every element of the claim" (MPEP §2131). Therefore, the absence of any disclosure by Thomas et al of binding (i.e., agglutination) between the nucleic acid and the polypeptide through a nucleic acid-binding motif in the polypeptide would necessarily make this reference fail to anticipate the present invention. Further, based on the lack of a disclosure or suggestion of a method for measuring an antibody, Thomas et al must also fail.

Withdrawal of this ground of rejection is requested.

The rejections of Claims 33-40 under 35 U.S.C. §112, first paragraph, and of Claims 33-40 under 35 U.S.C. §112, second paragraph, is obviated in part by amendment.

The fundamental criticism underlying these grounds of rejection is the Examiner's position that Applicants have recited a method without any method steps. To address this issued, Applicants have amended Claim 33 to specifically indicate that steps in the method. In particular, Applicants note that the steps of the agglutination immunoassay are now recited in Claim 33.

MPEP §2164.04 states:

> "A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first

> paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."

At page 6, line 17 to page 9, line 20, the Applicants fully disclose the acceptable polypeptides and nucleic acids to be bound thereto, for use in the present inventive method. Moreover, on page 10, line 2 to page 12, line 2 the Applicants provide a detailed explanation of how to practice the inventive method. The utility of these methods is demonstrated at page 14, line 8 to page 47, line 8 where the Applicants present 17 Examples and 4 Reference Examples, which clearly provide adequate disclosure to fully enable the skilled artisan to practice the claimed invention.

In view of the foregoing, Applicants submit that the presently claimed invention would be readily apparent to the skilled artisan with the aid of the present specification. And, it is with this specification as a guide that the skilled artisan would be able to practice the methods of the present invention without undue experimentation.

For all the reasons set forth above, the present invention is believed to be in compliance with 35 U.S.C. §112, first paragraph. As such, withdrawal of this ground of rejection is requested.

The rejection of Claims 25-40 under 35 U.S.C. §112, second paragraph, are believed to be obviated by amendment.

The claims have been amended so as to be free of the criticisms set forth by the Examiner. Specifically, Claim 25 has been amended to clearly indicate that the agglutination is measured by measuring agglutination images consistent with Example 5 (page 28). More specifically, the agglutination immunoassay is to be corrected to those for measuring an antibody in a sample (see Example 5).

Applicants request withdrawal of this ground of rejection.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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